



FOR IMMEDIATE RELEASE

CLS Americas and Unio Health Partners Announce Clinical Study “Micro Ultra-Sound Guided Focal Laser Ablation of Low to Intermediate Risk Prostate Cancer”

Irvine, CA and San Diego, CA – April 25, 2023 – [Clinical Laserthermia Systems Americas, Inc.](#) (CLS), a leading provider of office-based, focal laser ablation (FLA) systems for urologists, today announced it has entered into an agreement with Genesis Research, LLC, an affiliate of Unio Health Partners, to conduct a Phase I clinical study titled, “Micro Ultra-Sound Guided, Transperineal Focal Laser Ablation of Low-to-Intermediate Risk Prostate Cancer.” The study recently received IRB approval and will utilize CLS’s [TRANBERG® Thermal Therapy System](#) for image-guided focal laser ablation in conjunction with Exact Imaging’s ExactVu™ micro-ultrasound platform to visualize and target areas of interest in the prostate. The TRANBERG system will deliver targeted, precisely controlled focal laser ablation treatment to those areas while preserving the surrounding healthy tissue. The principal investigator for the study will be Paul E. Dato, MD, Director of Clinical Trials at Unio Health Partners (formerly Genesis Healthcare Partners).

In the US, over a million prostate biopsies are performed every year identifying more than 250,000 men with prostate cancer. These patients need minimally invasive therapies as alternatives to the standard treatments that often carry long term harmful side effects. CLS is actively recruiting and working with clinical and commercial partners to enable high precision, minimally invasive targeted fusion laser ablation of prostate cancer tumors to be performed under local anesthesia in an office setting or clinic as well as hospitals.

“Unio is excited to begin this feasibility study with CLS Americas for a new, minimally invasive, office-based treatment for low-to-intermediate risk prostate cancer,” stated Franklin Gaylis, MD, FACS Executive Medical Director for Unio Health Partners. “Our goal is to develop and refine new treatments we can later expand to our clinics and physicians that are not only effective in treating prostate cancer, but do so with low risk of infection and minimal side effects such as erectile dysfunction and urinary incontinence. An added potential benefit of this treatment approach is a reduction in the cost of localized prostate cancer care”

“The ExactVu micro-ultrasound system is a new and exciting robust image guidance platform for urology offices and clinics,” stated Michael Magnani, president of CLS Americas. “Combined with our TRANBERG laser, urologists will be able to perform targeted, image-guided focal laser ablation

treatments of prostate tissue, such as tumors, in an office or clinic. We look forward to collaborating with our study partner to maximize the potential workflow and patient benefits of our two systems.”

”This new feasibility study will be the first to combine micro-ultrasound platform for image guidance with focal laser ablation therapy to treat malignant prostate tumors,” said Paul E. Dato, MD, Director of Clinical Trials at Unio Health Partners. ”Our initial research indicates that the CLS TRANBERG laser and ExactVu micro-ultrasound system are two highly complementary systems with the potential to treat patients effectively with minimal unwanted side effects. The treatment’s transperineal access and workflow is very similar to the ExactVu-guided prostate biopsy process with a similar recovery time for the patient.”

CLS History & Experience – Image-Guided, Focal Laser Ablation of Prostate Tumors

CLS’s TRANBERG® Thermal Therapy System with its accessories have been used to treat hundreds of prostate tumor patients in the US and EU using MRI guidance. The safety and diagnostic accuracy of fusion-guided prostate biopsies are well documented with strong global market growth. The treatment process and workflow for MR/US, fusion-guided focal laser ablation of prostate cancer tumors is very similar to the fusion-guided biopsy process with a similar recovery time for the patient.

TRANBERG® Thermal Therapy System

The TRANBERG Thermal Therapy System can be configured for MR/US fusion-guided procedures using real-time tissue temperature measurements for precise therapy and ablation control. It includes a desktop mobile laser unit, innovative non-cooled laser applicators, tissue temperature probes, and procedure-specific accessories. The TRANBERG system can be deployed in either a transperineal or transrectal approach. A [TRANBERG FLA Animation Video](#) of the system and procedure is available to watch.

About Exact Imaging

Exact Imaging (www.exactimaging.com) is the world’s leader in high-resolution micro-ultrasound systems enabling real-time imaging and guided biopsies in the urological market for prostate cancer. Exact Imaging’s ExactVu™ micro-ultrasound platform operates at 29 MHz and enables a whole new level of resolution with the benefits of ease of use, affordability, and is an extension of the current urological workflow. Using the Exact Imaging platform, urologists are able to visualize areas of interest in the prostate and specifically target biopsies at those areas. For those cases where MRI might assist, the **FusionVu™** micro-US/MRI fusion application operates on the ExactVu micro-ultrasound platform and facilitates fast, simple MRI fusion-based targeting with the guidance of the micro-ultrasound system’s 70-micron real-time resolution. The ExactVu micro-ultrasound system, including the FusionVu application, have received regulatory approval in the European Union (CE Mark), the United States (FDA 510(k)) and Canada (Health Canada medical device license).

About Unio Health Partners

Unio Health Partners (UHP), a differentiated Physician services platform, was founded in April 2021 with the partnership of Genesis Healthcare Partners (GHP). GHP's best-in-class clinical program covers three sub-specialties (urology, gastroenterology, and radiation oncology) and offers numerous ancillary services, including pathology lab and pharmacy/in-office dispensing. With continued affiliations, UHP now provides services to 180 providers operating out of more than 50 locations in the greater San Diego, Los Angeles and Bay areas. UHP is led by a highly accomplished management team and provides a full suite of management services to its affiliated practices.

UHP is a highly differentiated physician services platform established by Triton Pacific with the goal of transforming urology and gastroenterology care delivery across California. Unio partners with leading physician practices, creating a cohesive, quality-oriented clinical culture and facilitating best practice sharing across the platform. UHP's affiliated practices gain access to a broader suite of services, providing a meaningful benefit to both physicians and patients. UHP will continue to build significant size, scale, and geographic coverage that will enhance the platform's value proposition to all stakeholders.

About CLS Americas, Inc.

Clinical Laserthermia Systems Americas Inc, based in Irvine, CA, is responsible for the sales, commercial development, operations and clinical support for the TRANBERG® Thermal Therapy System and accessories for the US urology market. The powerful system provides minimally invasive, focal laser ablation treatments using MR or MR US Fusion for image guidance and has received FDA clearance in the US for soft tissue ablation, such as prostate tumors.

CLS Americas is a subsidiary of Clinical Laserthermia Systems AB (publ) headquartered in Lund, Sweden, which has subsidiaries in Germany, the US and Singapore. *For more information about CLS, please visit the Company's website: www.clinicallaser.com. **CLS Americas Contact:** Phone: +1 (949) 504-5440, E-mail: contact-us@clinicallaser.com.*

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